

**AMENDMENTS TO THE DRAWINGS**

The attached sheets of drawings are lighter copies of Figures 2 and 4.

No new matter has been added.

## **REMARKS**

### ***Status of the Claims***

Claims 1-22 are currently pending in the present application. The Office Action is non-final. Claims 1, 4, 7-8, 10-14 and 16-17 have been amended without prejudice or disclaimer. The amendment to claim 12 is supported on page 9, line 1 of the specification. Claim 22 is new. Support for claim 22 can be found on page 5, lines 11 to 15, of the present specification. No new matter has been added by way of new or amended claims, because the new and amended claims are supported by the present specification. The amendments to the claims further define and clarify the structure of the present invention.

Based upon the above considerations, entry of the present amendment is respectfully requested.

### ***Issue Regarding Drawings***

The Examiner indicated that Figures 2 and 4 were not clear and it is hard to see the SDS-Page profiles of the protein purifications. Applicants on this date are submitting replacement drawings of Figures 2 and 4 as requested by the Examiner.

Applicants respectfully request reconsideration and subsequent entry of the replacement drawings.

### ***Claim Objections***

Claims 7-14 and 17-20 are objected to due to the claims are in improper multiple dependent form.

Applicants have amended claims 7-8, 10-14 and 17, without prejudice or disclaimer, to proper dependent form.

Applicants respectfully request reconsideration, withdrawal of the objection and subsequent examination of claims 7-14 and 17-20 on their merits.

Claim 16 is objected to due to informalities.

Applicants have amended claim 16, without prejudice or disclaimer, to depend upon claim 15.

Applicants respectfully request reconsideration and subsequent withdrawal of the present objection.

***Rejection Under 35 U.S.C. § 112, Second Paragraph, Indefiniteness***

Claims 1-6, 15 and 21 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The Examiner states that claim 1 is vague and indefinite since the last line of claim 1 recites the phrase “substantially purified.”

Applicants have amended claim 1, without prejudice or disclaimer, to remove “substantially purified” from claim 1. Applicants believe that this amendment should resolve the rejection in regards to claims 2-6, 15 and 21.

In regards to claim 4, the Examiner states that the claim is indefinite since claim 4, line 3, refers to different protein purification steps, then ends with the phrase “or any combination

thereof.” The Examiner states that the claim is indefinite because purification steps follow a sequential order; and the ending phrase is confusing because it disrupts the order of steps.

Applicants have amended claim 4, without prejudice or disclaimer, to remove “or any combination thereof” from the claim as the Examiner suggested.

Applicants respectfully request reconsideration and subsequent withdrawal of the present rejection.

***Rejection Under 35 U.S.C. § 102(b), Anticipation***

Claims 1-6, 15-16 and 21 stand rejected under 35 U.S.C. § 102(b) as anticipated by Shani *et al.*, U.S. Patent No. 6,331,416 (hereinafter “Shani *et al.*”).

The Examiner suggests that Shani *et al.* anticipates for teaching all the claim limitations. The Examiner suggests that this is exemplified in Figure 1, which describes all the essential steps of protein purification comprising homogenization of transgenic plant material, inherent step of separating the solids and binding soluble (containing fusion protein) to a cellulose binding or affinity column, washing and release of the fusion protein by varying the elution buffers to yield the fusion protein or recombinant protein as required. The Examiner further suggests that various column chromatography methods and matrices are described depending upon the requirements of the purification.

In addition the Examiner suggests that Shani *et al.* describes that the cellular binding domain or protein can be obtained from a variety of sources including enzymes and other proteins which bind to cellulose. Applicants respectfully traverse.

The present invention is distinguished from Shani *et al.* since Shani *et al.* does not disclose steps (b) through (f) for a method for production and purification of a soluble heterologous fusion protein comprising a cellulose binding module (CBM), from transgenic plants or transgenic plant cells expressing the fusion protein. Applicants describe each distinction below.

(b) adding an extraction liquid to the plant material, thereby creating a mixture of soluble and insoluble plant material, so as to extract the soluble fusion protein from said disrupted plant material to the liquid phase to obtain a protein extract

In Shani *et al.*, the plant is homogenized to bring the fusion protein into contact with the cellulosic matter to form a fusion protein cellulosic matter complex (see Shani *et al.*, col. 8, lines 49-56). Therefore, the fusion protein in Shani *et al.* binds to and becomes a part of the insoluble cellulosic matter complex, and of course, will not be extracted to the liquid phase to obtain a protein extract.

(c) separating the insoluble plant material, comprising cell-wall material and solids, from the protein extract comprising said fusion protein of interest

As stated earlier, Shani *et al.* obtains an insoluble cellulosic matter complex having fusion protein bound thereon. Therefore, the reference does not teach the separation of the insoluble plant material from the protein extract in step (b).

(d) contacting the protein extract to a polysaccharide matrix which binds to said fusion protein

Shani *et al.* is silent on any polysaccharide matrix which binds to a fusion protein. None of the steps in Fig. 1 of Shani *et al.* teaches step (d).

(e) washing the matrix with the bound fusion protein with one or more suitable aqueous solutions

The only “washing step” in Shani *et al.* is performed on cellulosic matter complex originated from the plant itself, not the polysaccharide matrix as presently claimed (see Shani *et al.*, col. 8, lines 68 to col. 9 line 7). Shani *et al.* describes this washing step as being used to remove unbound material in particular, endogenous plant proteins from the cellulosic matter complex and that this washing step can be repeated to “efficiently effect the removal of unbound matter” (*Id.*). Shani *et al.* would throw away the present invention during this washing procedure. Shani *et al.*, therefore does not teach step (e).

(f) eluting the fusion protein from said polysaccharide matrix by adjusting condition effecting the release of said fusion protein from the matrix

Since Shani *et al.* fails to teach the use of polysaccharide matrix to capture the fusion protein of interest, it cannot teach eluting the protein from the matrix. Shani *et al.* indicates that the cellulosic matter complex be washed in a column housing (see Shani *et al.*, col. 9 line 10-12). This is vastly different from the present invention since in Shani *et al.* the fusion protein of interest would be washed away with the endogenous plant proteins and other unbound material. Shani *et al.* then does not describe taking the wash and applying it to a polysaccharide matrix to

capture the fusion protein of interest since Shani *et al.* did not want the wash which included the unbound plant endogenous proteins.

In conclusion, Shani *et al.* does not anticipate the present invention for failing to disclose or suggest any of steps (b)-(f). In addition, we refer to the last paragraph of page 4 of the description in the present specification, which particularly highlights the difference, as well as the disadvantage of Shani *et al.* Instead of extracting the protein after plant disruption, Shani *et al.* employs a poorly-defined cellulosic matter which binds to the fusion-protein. The separation of the protein has the disadvantage of necessitating drastic conditions which may denature the protein to be purified. The present invention, on the other hand, has the advantage of providing a non-denaturing purification process.

Because “a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference,” the cited Shani *et al.* reference cannot be a basis for a rejection under § 102(b). See *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Thus, because of the lack of disclosure of all features as instantly claimed, the rejection in view of Shani *et al.* is overcome.

In regards to a potential future obviousness rejection, based upon the above, Applicants believe that one skilled in the art would not be motivated by the teachings or suggestions of Shani *et al.* towards the present invention.

Applicants respectfully request reconsideration and subsequent withdrawal of the present rejection.

**CONCLUSION**


In view of the above amendment, Applicants believe the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Paul D. Pyla, Reg. No. 59,228, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

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Attachments: Corrected Formal Drawings